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DATE MAILED: 06/11/2010

### NOTICE OF ALLOWANCE AND FEE(S) DUE

22428 7590 06/11/2010
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW

WASHINGTON DC 20007

EXAMINER
HEARD, THOMAS SWEENEY
ART UNIT PAPER NUMBER
1654

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/805,788      | 03/22/2004  | Steven C. Quay       | 054822-0117         | 9945             |

TITLE OF INVENTION: NASAL CALCITONIN FORMULATIONS CONTAINING CHLOROBUTANOL

| APPLN. TYPE    | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(8) DUE | DATE DUE   |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | YES          | \$755         | \$300               | \$0                  | \$1055           | 09/13/2010 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and I/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

| appropriate. All further<br>indicated unless corrects<br>maintenance fee notifica   | ed below or directed oth   | ng the Patent, advance<br>nerwise in Block 1, by   | orders and notification<br>(a) specifying a new o   | of n  | naintenance fees w<br>pondence address;   | ill be<br>and/or                               | mailed to the current<br>(b) indicating a sepa   | correspondence address as<br>rate "FEE ADDRESS" for  |
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|   | ENCE ADDRESS (Note: Use Bi   | ock 1 for any change of address  | )   | Feet  | <ul><li>s) Transmittal. Thi</li></ul>   | s certil                                       | icate cannot be used for   | domestic mailings of the<br>or any other accompanying<br>of tor formal drawing, must   |
| 22428   |  | /2010  |   |   | Cer   | tificate                                       | of Mailing or Trans  | mission  |
| SUITE 500<br>3000 K STREET  |  |  |   | I her<br>State<br>addr<br>trans               | reby certify that the<br>es Postal Service we<br>essed to the Mail<br>smitted to the USP                    | is Fee(<br>ith sul<br>Stop<br>TO (57           | s) Transmittal is being<br>ficient postage for firs<br>ISSUE FEE address<br>I) 273-2885, on the da                             | deposited with the United<br>t class mail in an envelope<br>above, or being facsimile<br>tte indicated below.                                    |
| WASHINGTON  | I, DC 20007  |  |   |   |   |  |  | (Depositor's name)   |
|   |  |  |   |   |   |  |  | (Signature)  |
|   |  |  |   |   |   |  |  | (Date)   |
| APPLICATION NO.   | FILING DATE  |  | FIRST NAMED INVEN   | TOR   |   | ATTO   | RNEY DOCKET NO.  | CONFIRMATION NO.   |
| 10/805,788  | 03/22/2004   |  | Steven C. Quay  |   |   |  | 054822-0117  | 9945   |
| TITLE OF INVENTION  | : NASAL CALCITONE  | N FORMULATIONS C   | ONTAINING CHLOR   | OBU   | TANOL   |  |  |  |
| APPLN, TYPE   | SMALL ENTITY   | ISSUE FEE DUE  | PUBLICATION FEE I   | OUE   | PREV. PAID ISSUE  | SFEE   | TOTAL FEE(S) DUE   | DATE DUE   |
| nonprovisional  | YES  | \$755  | \$300   |   | \$0   |  | \$1055   | 09/13/2010   |
| EXAM  | IINER  | ART UNIT   | CLASS-SUBCLASS  | S   |   |  |  |  |
| HEARD, THOM   |  | I654   | 530-307000  |   |   |  |  |  |
|   | ondence address (or Cha<br>B/122) attached.<br>ication (or "Fee Address'<br>12 or more recent) attach  | inge of Correspondence   | (I) the names of to<br>or agents OR, alte<br>(2) the name of a  | up to<br>rnativ<br>single<br>y or a<br>t atto | e firm (having as a<br>gent) and the name<br>meys or agents. If   | t attori                                       | era 2  |  |
| (A) NAME OF ASSI  | less an assignee is ident<br>h in 37 CFR 3.11. Comp<br>GNEE  | ified below, no assigne<br>oletion of this form is N   | e data will appear on t<br>DT a substitute for filin<br>(B) RESIDENCE: (6                                       | the page and CITY                             | atent. If an assigna<br>assignment.<br>and STATE OR C   | OUNT   | 'RY)   | scument has been filed for   |
| Please check the appropr  | iate assignee category or  | categories (will not be  | printed on the patent):   |   | Individual  | rporati  | on or other private gro  | up entity Government   |
| Advance Order -   | vo small entity discount p   | permitted)   | 4b. Payment of Fee(s):  A check is enclor Payment by cred The Director is hoverpayment, to !                    | sed.<br>it can<br>ereby                       | d. Form PTO-2038  | is atta  | ched.<br>required fee(s), any det  |  |
| 5. Change in Entity Sta   | tus (from status indicate<br>s SMALL ENTITY statu  |  | ☐ b Apolicant is n  | o Ioni  | ser claiming SMAI   | LEN  | ITTY status. See 37 CF   | TP 1 27(a)(2)  |
| - 11  |  |  |   |   |   |  |  | e assignee or other party in   |
| interest as snown by the  | records of the United Sta  | tes Patent and Tradema   | k Onice.  |   |   |  |  |  |
| Authorized Signature  |  |  | Date  |   |   |  |  |  |
| Typed or printed name   |  |  | Registration No.  |   |   |  |  |  |
| This collection of inform<br>an application. Confiden<br>submitting the completes<br>this form and/or suggesti<br>Box 1450, Alexandria, V<br>Alexandria, Virginia 223 | nation is required by 37 C<br>tiality is governed by 35<br>d application form to the<br>ions for reducing this but<br>'irginia 22313-1450. DC<br>it3-1450. | CFR 1.311. The informat<br>U.S.C. 122 and 37 CFI<br>USPTO. Time will var<br>den, should be sent to t<br>O NOT SEND FEES OR | ion is required to obtain  1.14. This collection  y depending upon the  the Chief Information C  COMPLETED FORM | n or r<br>is est<br>indiv<br>Office<br>IS TO  | etain a benefit by the<br>imated to take 12 r<br>idual case. Any co<br>r, U.S. Patent and<br>D THIS ADDRESS | he pub<br>minute:<br>mment<br>Trader<br>i. SEN | ic which is to file (and<br>to complete, including<br>s on the amount of tin<br>nark Office, U.S. Depa<br>D TO: Commissioner f | by the USPTO to process)<br>g gathering, preparing, and<br>ne you require to complete<br>atment of Commerce, P.O.<br>for Patents, P.O. Box 1450, |

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| 10/805,788                   | 03/22/2004      | Steven C. Quay                  | 054822-0117           | 9945             |  |  |
| 22428                        | 7590 06/11/2010 |                                 | EXAMINER              |                  |  |  |
| FOLEY AND LARDNER LLP        |                 |                                 | HEARD, THOMAS SWEENEY |                  |  |  |
| SUITE 500                    |                 |                                 | ART UNIT              | PAPER NUMBER     |  |  |
| 3000 K STREET<br>WASHINGTON, |                 | 1654<br>DATE MAILED: 06/11/2010 |                       |                  |  |  |

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 249 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 249 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

## Application No. Applicant(s) 10/805,788 QUAY ET AL. Notice of Allowability Examiner Art Unit THOMASS HEARD 1654 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to proposed Examiner's amendment, 5/25/2010. The allowed claim(s) is/are 3-8,12,16 and 20-30. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) $\square$ All b) ☐ Some\* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). \* Certified copies not received: \_\_\_\_\_. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. | Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date Information Disclosure Statements (PTO/SB/08). 7. X Examiner's Amendment/Comment Paper No./Mail Date 4. T Examiner's Comment Regarding Requirement for Deposit 8. T Examiner's Statement of Reasons for Allowance of Biological Material

/Thomas S Heard/

Examiner, Art Unit 1654

Supervisory Patent Examiner, Art Unit 1654

Other .

/Cecilia Tsang/